

AMENDMENTS TO THE DRAWINGS

The attached "Replacement Sheet" of drawings includes changes to Figures 1 and 2. The attached "Replacement Sheets," which includes Figures 1 and 2, replaces the original sheet including Figures 1 and 2.

Attachment: Replacement Sheet, Page 1/4

REMARKS

Claims 1, 2, 4, 5, 7-10, 12, 13, and 39-44 are now pending in the application. Claims 1, 2, 4, 5, 7-10, 12, and 13 stand rejected. Previously-withdrawn Claims 6, 11 and 14-38 have been cancelled herein, along with Claim 3; Claims 1 and 13 have been amended; and Claims 39-44 are newly presented. Support for the new claims and the amendments can be found throughout the application, drawings and claims as originally filed and, as such, no new matter has been presented. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

APPLICANTS INTERVIEW SUMMARY

Applicant thanks Supervisor Mickey Yu for speaking to Erica Schaefer on Wednesday, March 1, 2006. During the conversation, the cited art and pending claims were discussed. No particular agreement was reached regarding the pending claims or the cited art.

DRAWINGS

Figures 1 and 2 have been amended to correct minor informalities. In Figure 1, reference number 52 on the plunger has been changed to 54; and in Figure 2, the reference number 60 and the reconstituting fluid has been added to the second container 16. As these features were included in the specification as filed, no new matter has been presented. The Examiner's approval of these drawings is respectfully requested.

REJECTION UNDER 35 U.S.C. § 112

Claim 13 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant has non-narrowingly amended Claim 13 to overcome this informality. Reconsideration and withdrawal of this rejection is respectfully requested.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-3, 5, 7-9, and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's Background in view of Ronk (U.S. Pat. No. 5,951,160; hereinafter "Ronk") and Reprogenesis (WO Pat. No. 01/08630; hereinafter "Reprogenesis"). Claims 4 and 10 stand rejected as being unpatentable over references applied above with respect to Claim 1, and further in view of Official Notice. Claim 13 stands rejected as being unpatentable over references applied above with respect to Claim 1, and further in view of Safabash et al. (U.S. Patent No. 5,908,054; hereinafter "Safabash"). Since Claim 3 has been cancelled, the rejection thereto has been rendered moot. With regard to Claims 1, 2, 4, 5, 7-10, 12, and 13, these rejections are respectfully traversed.

Initially, Applicant notes that none of Applicant's Background, Ronk, Reprogenesis or Safabash, either singly or in combination, discloses a sealing apparatus including a valve for drawing a negative pressure on a chamber, or a second container for maintaining a negative pressure within a first container. In this regard, independent Claim 1 recites:

an allograft contained within the chamber, the first container maintaining a negative pressure within the chamber; and

a second container enclosing the first container and maintaining a negative pressure therein,

wherein the first sealing device includes a valve for drawing the negative pressure on the chamber.
(emphasis added)

In contrast, Ronk discloses an apparatus 10 for mixing and delivering bone cement that includes a second container 16 selectively coupled to a flexible bag 12 via a retaining disk 50. The retaining disk 50 can be coupled to the flexible bag 12 via a groove 52 formed on the retaining disk 50. The retaining disk 50 is coupled to the second container 16 via a female leur fitting 40, a male leur fitting 38, a stopcock 26, and a female leur fitting 28. Ronk does not disclose a first sealing device including a valve for drawing a negative pressure on the chamber, or a second container for enclosing the first container and maintaining a negative pressure therein, as claimed in Applicant's independent Claim 1.

Reprogenesis discloses an inner container 20 enclosed by an outer container 22 and fluidly coupled to the outer container 22 via a detachable fluid-conducting conduit 24. Reprogenesis also discloses placing instruments within the outer container 22 adjacent to the inner container 20. Nevertheless, Reprogenesis does not disclose whatsoever a container for enclosing the first container and maintaining a negative pressure therein, or the use of a valve for drawing a negative pressure on the chamber, as claimed in Applicant's independent Claim 1.

Safabash discloses a fluid transfer assembly 2 that uses two syringes 38, 50 coupled with a leur lock element 10 for flowing a fluid 38 into a gel 58. Safabash also

discloses that exit holes 22 can be used to evenly disperse the fluid 38 within the gel 58, but does not disclose a valve for drawing a negative pressure on a chamber, or a second container for enclosing the first container and maintaining a negative pressure therein, as claimed in Applicant's independent Claim 1.

In view of the above discussion, Applicant respectfully submits that at least these features as claimed are not taught or suggested whatsoever by Applicant's Background, Ronk, Reprogenesis or Safabash, either singly or in combination. First, none of Applicant's Background, Ronk or Safabash discloses whatsoever a valve for drawing a negative pressure within a chamber of a first container, as claimed herein. Ronk, in contrast, discloses drawing a vacuum on the second container 20 by moving the plunger 56 upward to draw the bone cement into the second container 16. Second, Reprogenesis does not disclose a container for enclosing a first container and maintaining a negative pressure within a chamber of the first container; and, further, Applicant submits that it is improper for the Examiner to modify Ronk to include the container of Reprogenesis, as there is no teaching or suggestion of the desirability of this modification. Moreover, Ronk teaches away from the desirability of this modification, as the packaging of Reprogenesis is designed to transport biological fluids that cannot be sterilized through traditional sterilization techniques into and through non-sterile areas, in contrast to the apparatus of Ronk, which can be sterilized through traditional sterilization techniques.

Accordingly, Applicant respectfully submits that the combination of Applicant's Background, Ronk, Reprogenesis and Safabash does not teach or suggest each element of Applicant's independent Claim 1 and, further, Applicant notes that these references teach away from such a combination. Thus, Applicant respectfully requests

that the Examiner reconsider and withdraw the rejection of Claim 1 under 35 U.S.C. 103(a). With regard to Claims 2, 4, 5, 7-10, 12 and 13, Applicant notes that these claims depend directly or indirectly from independent Claim 1 and, thus, should be in condition for allowance for the reasons set forth for Claim 1 above. Therefore, Applicant respectfully requests the Examiner reconsider and withdraw the rejection of Claims 2, 4, 5, 7-10, 12 and 13 under 35 U.S.C. 103(a).

NEW CLAIMS

Applicant has added new Claims 39-44. Support for newly added Claims 39-44 can be found throughout the specification, drawings and claims as originally filed. Applicant respectfully submits that new Claims 39-44 are also not taught or suggested by Applicant's Background, Ronk, Reprogenesis or Safabash, either singly or in combination. Specifically, independent Claim 39 recites a valve for drawing a negative pressure within a first syringe and independent Claim 41 recites a container including a cavity that includes a first container and a second container, with a first sealing device including a valve for drawing a negative pressure on the chamber of the first container. As discussed previously, none of Applicant's Background, Ronk, Reprogenesis or Safabash teaches or suggests these features as claimed herein. Accordingly, Applicant believes Claims 39-44 are patentable and in condition for allowance.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is

believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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